K111273

NOV - 8 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

1. Submitter Information

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2. Subject Device Information

Type of 510(k) submission:	Traditional
Common Name:	Powered heating pad and infrared lamp
Trade Name:	FIR Heat Therapy Systems
Models:	EH-6601, EH-6603, EH-6604, EH-6605, EH-6606, EH-6607, EH-6608, EH-6609, EH-6610, EH-6611, EH-6612, EH-6613, EH-6614
Classification Name:	Powered heating pad and infrared lamp
Review Panel:	Physical Medicine
Product Code:	IRT, ILY
Regulation Number:	CFR 890.5740, 890.5500
Regulation Class:	2

3. Predicate Device Information

Sponsor:	EAS Consulting Group LLC.
Device Name:	Thermotex Heat Therapy Systems
510(k) Number:	K092589
Product Code:	IRT, ILY
Regulation Number:	CFR 890.5740, 890.5500
Regulation Class:	2

4. Device Description

The FIR Heat Therapy Systems provide infrared heat to different areas of the patient's body. The Systems consist of an outer application cover with adjustable pads that enclose the infrared heating elements to treat different areas of the body. The pad's covers are fabricated of nylon-cotton blend. Velcro fasteners on the cover allow for adjusting the cover and pads for optimum contact to the patient's body areas.

5. Intended Use

The FIR Heat Therapy Systems are indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains and minor muscular back pain; muscular relaxation; and the temporary increase of local circulation where applied.

6. Conformity Standards

The manufacturer has evaluated the subject device by lab testing according to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2007
- ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, 2009
- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity, 2002+A1:2006

7. Determination of Substantial Equivalence

Compare with predicate device, the subject device is very similar in design principle, intended use, indication for use, the applicable standards, infrared electromagnetic spectrum and therapeutic temperature range.

The difference for the key specifications listed in the following table will not affect the safety and effectiveness for the subject device.

Item	Predicate Device	Subject Device	Note
Device Name	Thermotex Heat Therapy Systems	FIR Heat Therapy Systems	--
Design Principle	FIR (far-infrared) therapy	FIR (far-infrared) therapy	Same
Patient Contacting Material	Velours (nylon face cover, 50/50 nylon/cotton back)	Nylon-cotton blend pad ABS plastic cover Nylon Velcro fastener	Note 1
Energy Source	110Vac, 50W	6Vdc (4 x "AA" alkaline batteries), 8W (maximum)	Note 2
Heating Element	Carbon black fiberglass (glass-fabric impregnated with electric conducting plastic "PTFE-Carbon")	Carbon fibre	Note 3
Infrared Electromagnetic Spectrum	5~15 microns, with center around 9 microns	5~15 microns, with center around 9 microns	Same
Therapeutic Temperature Range	40~45 °C	40~45 °C	Same
Approximate Skin Temperature	44 °C (for Low setting)	41~42 °C	Note 4
Time to Maximum Temperature	--	10 minutes	
Time to Reach Therapeutic Temperature Range	--	5 minutes	
Recommended Treatment Time	30-45 minutes	30-45 minutes	Same

Note 1:

Although the patient contacting material of subject device is different from the predicate device, both of them are complied with ISO 10993-1. So this difference will not raise any safety or effectiveness issue.

Note 2:

Although the power supply of subject device is different from the predicate device, both of them are complied with IEC 60601-1. So this difference will not raise any safety or effectiveness issue.

Note 3:

Carbon black fiberglass is an E-Glass that is woven and dyed black to look like a 3K Twill Weave carbon fiber. The carbon black fiberglass does not have the strength properties of a real carbon fiber. But their far infrared thermal specification is similar, so this difference will not raise any safety or effectiveness issue.

Note 4:

Although Approximate Skin Temperature and Time to Reach Temperature Range of predicate device are different from the predicate device, they are both in the FDA generally considering therapeutic temperature range 40-45°C, so this difference will not raise any safety or effectiveness issue.

8. Performance Testing

We have provided the performance tests including the skin temperature test and the infrared energy and spectrum test to support the safety and effectiveness of the subject device.

The spectrum test shows that the subject device emits the main infrared electromagnetic spectrum 5~15 microns, with center around 9 microns.

The infrared energy test (Thermal Distribution Map) shows that the core temperature range of heating pad is about 44°C.

The skin temperature test shows that the time for skin surface to reach therapeutic temperature range 40°C is about 5 minutes; the time to reach maximum temperature 42°C is about 10 minutes.

9. Conclusion

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject devices are substantially equivalent to the predicate devices.

10. Summary Prepared Date: 3 November 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% MEDLAB (Shenzhen) Information Service Co., Ltd.
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NOV - 8 2011

Re: K111273
Trade/Device Name: FIR Heat Therapy Systems, models: EH-6601, EH-6603, EH-6604, EH-6605, EH-6606, EH-6607, EH-6608, EH-6609, EH-6610, EH-6611, EH-6612, EH-6613, EH-6614
Regulation Number: 21 CFR 890.5740
Regulation Name: Powered heating pad
Regulatory Class: Class II
Product Code: IRT, ILY
Dated: October 19, 2011
Received: October 26, 2011

Dear Ms. Wei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 3. Indications for Use

Indications for Use

510(k) Number (if known):

Device Name: FIR Heat Therapy Systems, models: EH-6601, EH-6603, EH-6604, EH-6605, EH-6606, EH-6607, EH-6608, EH-6609, EH-6610, EH-6611, EH-6612, EH-6613, EH-6614

Indications for Use:
The FIR Heat Therapy Systems are indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains and minor muscular back pain; muscular relaxation; and the temporary increase of local circulation where applied.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111273